אפריל 2022

רופא /ה, רוקח/ת נכבד/ה

חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר

גמסיטאבין טבע תמיסה מרוכזת, תמיסה מרוכזת להזרקה

Gemcitabine Teva concentrate, concentrate for solution for infusion

Contains: 40 mg/ml, *gemcitabine (as hydrochloride)*

עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

Non-Small Cell Lung Cancer:
Gemcitabine Teva 40 mg/ml Concentrate for Solution for Infusion is indicated for the palliative treatment of patients with locally advanced or metastatic non-small cell lung cancer.

Breast cancer:
Gemcitabine Teva 40 mg/ml Concentrate for Solution for Infusion in combination with paclitaxel,is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated.

Pancreatic Cancer:
Gemcitabine Teva 40 mg/ml Concentrate for Solution for Infusion is indicated for the treatment of patients with locally advanced or metastatic adenocarcinoma of the pancreas and for patients with 5-FU refractory pancreatic cancer.

Bladder Cancer:
Gemcitabine Teva 40 mg/ml Concentrate for Solution for Infusion is indicated for the treatment of patients with bladder cancer at the invasive stage.

Ovarian cancer:
Gemcitabine Teva 40 mg/ml Concentrate for Solution for Infusion in combination with carboplatin, is indicated for the treatment of patients with recurrent epithelial ovarian carcinoma who have relapsed at least 6 months after platinum-based therapy.

ברצוננו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):

[...]
4.4 Special warnings and precautions for use
[...]
~~Sodium~~

~~Gemcitabine contains 3.95 mg (<1 mmol) sodium per ml concentrate. This should be taken into consideration by patients on a controlled sodium diet.~~

~~Ethanol~~

~~Gemcitabine contains 395 mg ethanol per ml concentrate. This can cause alcohol related adverse reactions if not diluted properly. The instructions on dilution of the product should be followed carefully (see section 6.6). This may also be harmful in patients suffering from alcoholism and should also be taken into consideration in high-risk groups such as patients with liver disease or epilepsy. Consideration should be given to possible effects on the central nervous system and other effects.~~
[...]

6.1 List of excipients

~~Ethanol absolute~~
~~Sodium hydroxide~~
~~Disodium phosphate anhydrous~~
Hydrochloric acid
Water for injections
[...]

6.3 Shelf life after first opening

After first opening

Chemical and physical in use stability has been demonstrated for 28 days at 25°C.

From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions ~~prior to use~~ are the responsibility of the user.

Stability after dilution

Chemical and physical in-use stability has been demonstrated for 28 days at 2°C to 8°C and about 25°C upon ~~after~~ dilution in 0.9% sodium chloride solution to a final concentration in the range between 2 – 25 mg/ml (2.0 mg/ml, 12 mg/ml and 25 mg/ml). The pH of the diluted solution is in the range of 2-3 and the osmolality is approximately 285 mOsm/kg. Diluted solutions are stable when packaged into either PVC or PE infusion bags.
~~(5.2 mg/ml gemcitabine) has been demonstrated for 5 days at 2°C to 8°C and for 5 days up to 30°C.~~
From a microbiological point of view, the solution for infusion should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C unless ~~are the responsibility of the~~ user dilution has taken ~~should take~~ place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Store at 2°C - 8°C in the original package .~~Store in the original package~~
~~Store below 25°C. Do not freeze or refrigerate~~
[...]

6.6 Special precautions for disposal and other handling

Handling
The normal safety precautions for cytostatic agents must be observed when preparing and disposing of the infusion solution. Pregnant personnel should not handle the product. Handling of the solution for infusion should be done in a safety box and protective coats and gloves should be used. If no safety box is available, the equipment should be supplemented with a mask and protective glasses.
[...]

Instructions for dilution

The only approved diluent for dilution of Gemcitabine Teva concentrate for solution for infusion is sodium chloride 9 mg/ml (0.9%) solution for injection (without preservative).
~~The following instructions for dilution should be strictly followed in order to avoid adverse events.~~

- Use aseptic technique during dilution of gemcitabine for intravenous infusion administration.

~~The total quantity of gemcitabine 40mg/ml concentrate for solution for infusion required for an individual patient should be diluted into at least 500 ml of sterile sodium chloride 9 mg/ml (0.9%)~~

~~solution for injection (without preservative) and infused over 30 min. Further dilution with the same diluent can be done.~~

- Diluted solution is a clear colourless or light straw-coloured solution.
- Parenteral medicinal products should be inspected visually for particulate matter and discolouration prior to administration. If particulate matter is observed, do not administer.

Any unused product or waste material should be disposed of in accordance with local requirements.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

https://israeldrugs.health.gov.il, וניתן לקבלו מודפס ע"י פניה לחברת טבע.